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African-American (AA) women have the highest breast cancer mortality rate in the U.S. Despite reports suggesting that breast cancer in AA women might be a biologically more aggressive disease, AA women, especially postmenopausal AA women, remain one of the least studied populations in this country, with very little known about their sex hormone profile. Recent findings have suggested that body fat distribution may be a better marker for breast cancer risk than degree of obesity. This is a 5-year cross-sectional study to determine the association between body fat phenotypes and sex hormone profile in postmenopausal AA women. For year three, we were able to continue aggressive recruitment strategies to increase the total number of women interested in participating in the study from 459 for year two to 729. This continues to be a very challenging study to undertake, but our study team is undeterred. To date 29 of 50 eligible women have gone through the study protocol. Hormone values for all 29 of these women have already been determined. Results from preliminary analyses of hormone and other data on women who have completed the study protocol are presented in this report.

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INTRODUCTION:

Breast cancer is a major public health concern for African-American (AA) women in the U.S. AA women experience higher breast cancer mortality rates as well as higher prevalences of obesity and upper body adiposity than Caucasian women. Despite reports suggesting that breast cancer in AA women might be a biologically more aggressive disease, AA women, especially postmenopausal AA women, remain one of the least studied populations in this country, with very little known about their sex hormone profile. Recent findings have suggested that body fat distribution may be a better marker for breast cancer risk than degree of obesity. In this study, we will test the hypotheses that postmenopausal AA women with normal versus upper body fat phenotypes have a sex hormone profile associated with the lowest and highest risk of breast cancer, respectively. This will be a 5-year cross-sectional study comprising 210 healthy postmenopausal AA women (one year postmenopausal up to age 70 years); 70 per body fat phenotype categories of lower (WHR$\leq$0.75), normal (0.75<WHR$\leq$0.80) and upper (WHR>0.80) body fat phenotypes (WHR is the waist to hip circumference ratio). Blood samples will be collected on two consecutive days for determination of estradiol, free estradiol, percent free estradiol, estrone, estrone sulfate, testosterone, free testosterone, percent free testosterone, androstenedione and sex hormone binding globulin, as well as follicular-stimulating hormone and luteinizing hormone. We will determine the subject's body mass index (BMI) and percent body fat using a Hologic Dual Energy X-ray Absorptiometry (DEXA) scanner and collect other relevant data to enable us to control for established and possible confounding factors such as: medical history including family history of breast cancer and a history of benign breast disease; reproductive history such as age at menarche, age at first birth, and number of children; dietary data; physical activity data and others such as use of alcohol, smoking, and exogenous hormones. Multivariate regression models adjusting for various confounders such as age, BMI or percent body fat, age at menarche, parity, and others such as age at first birth as well as various interaction terms between age and BMI, and age and body fat phenotypes, will be conducted to test our hypotheses. This study will add to the virtually non-existent data on sex hormone profile as it relates to postmenopausal breast cancer risk in normal, lower and upper body fat phenotype AA women, independent of body adiposity. It will help us determine whether or not the current thinking of a positive linear association between WHR and breast cancer risk is correct. If our hypotheses are true, future studies would need to control for body fat phenotype; otherwise study findings may provide misleading conclusions. Further, as body fat distribution is potentially modifiable by lifestyle factors such as diet, smoking, drinking alcohol, and physical activity, the possible identification of certain body fat phenotypes as a marker of a hormonal pattern that may increase breast cancer risk in women is of considerable importance.

BODY:

Statement of Work

Body Fat phenotypes, Sex Hormones, and Breast Cancer Risk in Postmenopausal African-American Women

Task 1. Set up study (Months 1 to 4)

- **inform collaborating bodies (such as the GCRC, NEMC[1], and BONREC[2]) of grant award, set up appointments, and finalize arrangements for conduct of the study using their services**— Accomplished according to schedule in year 1.

[1] GCRC, NEMC: General Clinical Research Center, New England Medical Center

[2] BONREC: Boston Obesity and Nutrition Research Center

- **start hiring process for the Research and Outreach Coordinators with the goal of hiring them by the 3rd month, and training the Research Coordinator by the 4th month**—Accomplished in year 1. Changes since last year's report is as follows. Ms. Cindy Neels was hired and trained as our Research Coordinator since February, 2002. Ms. Neels is a postmenopausal woman and is well suited to undertake this position both because of her qualifications and her ability to better relate to other postmenopausal women. Our previous Research Coordinator, Ms. Nikki Leiser, has taken another position, but has agreed to assist us as a back up Research Coordinator should our present Research Coordinator be overwhelmed with large volumes of telephone calls and the need to get women through the study protocol. Ms. Diane Wood continues to be our Outreach Coordinator and helped with recruitment activities at 50% time till April 2002 when funding for the Outreach Coordinator for our other similar study on premenopausal women ended. Nevertheless, Ms. Diane Wood, who is also a postmenopausal AA women, still continues to act as our Outreach Coordinator at 25% time. We have hired another postmenopausal AA woman on a part-time basis, Ms. Geneva Ruff, who was one of our study subjects to assist with telephone screening of women. Ms. Ruff will be helping us with telephone screening of women, as well as with recalling almost 400 women who have previously been telephone screened before but whose screening were not complete. Our previous protocol was to stop screening women once we knew they were not eligible to go through the study protocol. We have, however, received approval both from our Tufts Human Investigation Review Committee (Tufts HIRC) and the DOD HSRRB (Human Subjects Research and Review Board) to recall these women so that we will be able to publish valuable background information on this very little studied postmenopausal AA women population. This way, we will be able to get important information on this population with the money spent on recruiting women for this study, even though getting women through the actual study protocol is slow and very challenging.

  To ensure study continuity in the event that our Research Coordinator takes sick leave or vacation time, and to get additional help for our Research Coordinator in case of increased screening of interested women demands, we realize the need to have someone fill in for the Research Coordinator or to assist her in her duties. As stated above, our previous Research Coordinator Ms. Nikki Leiser has agreed to take on this back up role should this need arises. Currently, we have received approval by both the Tufts HIRC and the DOD HSRRB to undertake the inter-observer-variability component of this study.

- **purchase all supplies needed for year 1 and 2 of study** – Accomplished.

- **finalize, and make copies of all questionnaires, consent forms, and other materials needed for the study**—Accomplished as reported in year 1 progress report.

- **develop flyers, and other materials needed for recruitment of the target population, and get approval of the HIRC for use of these materials** – Accomplished as reported in year 1 progress report. Some minor changes to our flyer were made to allow us to recruit women above the age of 70 years who would qualify otherwise, and to include our study website on the flyer. These changes have been approved by both the Tufts HIRC and the DOD HSRRB last year.

Task 2. Recruit subjects and collect data (Months 5 to 54)

- **advertise study to the the AA postmenopausal population using various strategies (old and new), and established and new contacts within the AA community** – These activities are in progress but for this last year our recruitment activities were dampened for about 6 months. This is because, for this last year, with reorganization of our Tufts HIRC, and the hire of a new Director, our study protocol

was put on hold when we requested approval for our annual recertification last March. We were put on hold primarily because of the DOD requirement for us to include the statement in our consent form that Tufts would cover all medical care costs for a subject should a research-related injury be incurred to the subject going through the study protocol. Tufts has coverage for if the injury is due to negligence on the part of our staff but not beyond that. The latter was not acceptable to DOD. Our DOD grants officer had said that DOD would be able to cover the costs of insurance coverage for this if Tufts was able to obtain coverage by an insurance company. However, Tufts was not able to find an insurance company willing to provide such coverage. After a series of negotiations by all parties concerned, Tufts decided to allow this statement be put in the consent form primarily because of the fact that this is a low-risk study. Following this, we were also asked by the new Tufts HIRC committee to make some changes to our consent form. When the revised consent form was approved by our Tufts HIRC and then submitted to the DOD HSRRB, we were told that we needed to revise our consent form further to meet the new requirements of the DOD HSRRB. These changes were made and final approval was given by the DOD HSRRB and our DOD grants officer on September 24, 2002 – 6 months later!! Thus for 6 months of this third year, we were not able to recruit women for this study, pending approval of our consent form. We did not feel we could do all out recruitment because we already had 9 women on hold to get through the study protocol. We were concerned that women would begin to question our credibility should they be asked to wait without a set date for them to start going through the study protocol. Despite this major set back to our recruitment efforts, for this last year we were successful in getting an additional 270 women who called expressing interest to participate in the study.

We had gotten approval to put out combined advertisements for both the pre and postmenopausal studies. As such all study flyers going to premenopausal women also had information about our postmenopausal study. This gave us greater exposure to postmenopausal women through the premenopausal women. In addition we did combined advertisements in the newspapers, particularly the Boston Metro and the Banner, and in the public trains (the orange line). We also advertised at two train stations where a large proportion of the commuters are AAs (Downtown Crossing and Forest Hills T-stations). We did mass-mailings of flyers to more than 1,000 AA women who were Body by Brandy consumers, and on the mailing list of Boston Reach 2010. We also mailed out flyers to 57 public schools, and 14 senior centers in the Roxbury, Dorchester and Mattapan areas, 5 support/advocacy groups (Massachusetts Breast Cancer Coalition, The African Health Initiative, The New England Coalition for Breast Cancer Survivors, the Boston YWCA, and the Multicultural Coalition on Aging) These efforts were followed by follow-up telephone calls as well. We continued to send flyers to 29 libraries in the Boston area periodically. Flyers were also distributed periodically at the T-stations, malls, hair salons, restaurants, etc. In addition, we advertised at 4 cable TV stations.

The PI was invited for a live question and answer session on Radio One, and to speak at a Lupus and Breast Cancer Awareness Conference, and for other events/meetings about breast cancer in Black women and our research study. We also advertised in the National Black Nurses Association Newsletter and in a banquet brochure for the National Council of Negro Women. We were also represented at 41 events. These included various events at health centers (6) and at churches (8), as well as educational and community events (such as at Roxbury Community College, YWCA, Dorchester Women's Day Boston Healthy Start Initiative, Roxbury Multi-Service Center, Black Men's Health Fair, Black History Month Celebration,), street fairs (Caribbean Festival, Dudley Street Fair, International Festival, Kite Festival), advocacy groups (Massachusetts Million Women March Movement, Professional Business Women's group, Committee to end Elder Homelessness), and city sponsored events (Boston Department of Parks and Recreations, and the Mayor's Health Van). Flyers were also passed out at a concert and a circus largely attended by AAs. In addition we looked at the possibility of recruiting women through the prison system, but was told that to do so we needed to study health issues confined to women in prison. There were also other reasons put forth to us that did not make it feasible for us to recruit incarcerated women. We tried again to contact churches through the services of a Black minister's wife, and

contacted at least 50 churches asking if our study could be advertised in their church bulletins and if the ministers would help make announcements about the study after services. These efforts however did not seem to bring in the calls from women we were hoping they would.

A major recruitment effort we made this last year also came in the form of 'Breast cancer risk factors and healthy lifestyle' seminars which we conducted within the AA community last summer. These seminars were funded by the American Cancer Society (ACS) and the Tufts University College of Active Citizenship and Public Service (TUCCPS). Twenty-two seminars were conducted at health centers, community agencies, churches, and other community groups. Through these seminars we were able to distribute flyers to at least 300 women. The community educators who were mostly AA women trained by the ACS-funded project to educate women were also helping us distribute our study flyers. We also collaborated with Boston Reach 2010 whose women ambassadors helped inform women about our study as well as help distribute flyers to AA women in the community as they educate women on breast and cervical health issues within the community. In addition, recently we obtained approval from the Executive Office of Elder Affairs Elder Rights Review Committee to recruit their members for this study. We will expand our recruitment effort to take advantage of this approval for this coming year.

- **screen interested women for eligibility** -- This is also in progress. Currently, the total number of telephone calls received from interested women are 729 (Appendix 1). We are currently unable to reach 24 of these women (e.g., did not leave telephone numbers). We have already called 705 women with telephone numbers, and were able to reach 636 (90%) of these (134 were premenopausal women; this is probably due to the combined advertisements to recruit both pre and postmenopausal AA that we did for this year). Of the 502 postmenopausal women that we screened over the telephone, 71 were eligible, 47 were potentially eligible and 384 women were not eligible. Of those who do not qualify (N=384), reasons for ineligibility include having a disease (N=142; including 44 who were diabetic, 27 who had hypercholesterolemia, 20 heart disease, and 14 breast cancer), having first degree relatives with breast cancer (N=42), going into menopause due to surgery (N=114), and having various lifestyle and weight issues that render women ineligible (N=140). Forty-nine women changed their minds about participating. Numbers reported here are not static and change daily.

- **recruit eligible women into study (expected rate of recruitment is 46 per year for years 1, 2, 3 and 4, and 26 for year 5; total N=210)** -- To get the eligible women through the study protocol is another challenge. Of the 71 women who were eligible after telephone screening, only 50 women remained eligible at this time (7 changed their minds at a later date, 2 became ineligible after re-screening, 4 lost interest, and we were not able to contact 8) (Appendix 2). Of the net 50 women who are currently eligible, 29 have completed going through the study protocol (one completed only one day of blood drawing). Nine have not gone through the informed consent form process and have not gotten instructions on how to complete the various study questionnaires. Twelve are waiting to be scheduled for body measurements and blood drawing. These women (N=21) have been on hold because our consent form did not get approved for about 6 months for reasons mentioned above. Now that we have gotten approval to continue recruiting women, we will schedule these women to get through the study protocol as soon as possible.

Of the new eligible women this year, responses came from our advertisements in the Metro, the Banner, previous advertisement on WILD radio station, flyers in apartment buildings, word of mouth, community health centers and community events. Our current number of calls for the past 12 months averaged 22, with the a maximum of 57 calls and a minimum of 8 per month). The higher the volume of telephone calls we receive the more likely it is that we will get the number of eligible women going through the study protocol. The challenge and labor-intensive nature of conducting a research study in postmenopausal AA remain great. This would make findings on this hard to recruit population even more valuable, and much needed. Our study team continues to be committed to face the challenges that

this study brings to meet our study goals.

Task 3. Manage incoming data, preliminary analyses, and annual report writing (Months 5 to 54)

- **set up datafiles for medical history, socioeconomic, dietary intake, physical activity, anthropometric**—all of these datafiles have been setup.

- **enter and clean data, and undertake all data quality control measures (ongoing)** – we have entered and cleaned data for 29 of our study participants.

- **conduct preliminary analyses (once a year) for annual report** –we have undertaken preliminary analyses on data for all 29 of our study subjects. The tables of data on basic characteristics of all women, those who are obese, and non-obese, as well as those with lower, normal and upper body fat phenotypes are presented in Tables 1 to 6.

  Of the 29 women we have currently recruited for this study, 3 have lower body fat (LBF; WHR≤0.75), 13 normal body fat (NBF; 0.75<WHR≤0.80) and 13 have upper body fat (UBF; WHR>0.8) phenotypes women [17 were Non-Obese (BMI=<27) and 12 Obese (BMI>27]. Because of the small number of women we have recruited at this time in general, and specifically within each body fat phenotype, the findings reported here show possible trends as there is not much power for any conclusive findings. Also, for lack of power, we did not run multiple regression analyses on these data to compare levels of hormone between the different body fat phenotypes. Table 1shows the mean and S.D. of the age, age at menarche, age at menopause, age at first birth, number of children, height, weight, BMI and WHR of all 29 women. Using student's t-tests for unpaired variables, only BMI ($p=0.013$), and WHR ($p<0.0001$) were significantly higher in UBF compared to NBF phenotype women (Table 2). Further, only weight and BMI were significantly higher in Obese compared to Non-Obese women ($p<0.0001$ for both) (Table 2). Women within the different body fat phenotype categories, as well as within the Non-Obese and Obese categories, were also not found to be significantly different in their intake of the various macronutrients as shown in Tables 3 and 4. However, intakes of protein and percent calories from protein are close to significantly higher in Obese compared to Non-Obese women ($p=0.052$ and 0.055, respectively).

  Tables 4 and 5 show hormone data for all 29 women, for Non-Obese and Obese women, and for women within each of the body fat phenotype categories. Obese women had significantly higher levels of percent free estradiol (% Free E2) ($p=0.014$; by 17%), percent free testosterone (% Free T) ($p=0.022$; by 43%), lower sex-hormone binding globulin (SHBG) ($p=0.004$; by 75%) and lower level of follicular-stimulating hormone (FSH) ($p=0.004$; by 15%) compared to Non-Obese women (Table 4). With more numbers than reported last year, we now find that UBF phenotype women had significantly higher % Free E2 ($p=0.052$; by 14%) and % Free T ($p=0.021$; by 46%), and lower SHBG ($p=0.021$; by 61%). The androgenic/estrogenic hormonal profile found here between Obese and Non-Obese women, and between NBF and UBF phenotype women are indeed similar to those of women at high risk of breast cancer (1-3). Postmenopausal obesity is a known risk factor of breast cancer (4). There is growing evidence that women with upper body fat distribution are at a higher risk of breast cancer, and show a premalignant hormonal profile (5,6). Our preliminary findings, though non-conclusive due to the small numbers, however, do suggest that postmenopausal AA women who are obese, and who have upper body fat distribution do tend to have a distinct hormonal profile associated with increased risk of breast cancer.

- **prepare report at end of each project year**—Accomplished.

Task 4. Manage blood samples and ship samples for analysis of hormone levels (Months 5 to 54)

- **set up folder for storing blood sample records** –Accomplished.

- **store all blood samples till ready for shipment to Dr. Longcope's laboratory (samples will not be stored longer than 6 months prior to shipment)**—Blood samples for hormone determinations are stored at the GCRC, NEMC, at –70 degrees Centigrade.

- **ship blood samples to Dr. Longcope's laboratory for hormone analyses every 6 months** – Accomplished with serum samples from 29 women.

Task 5. Final analyses and report writing (Months 55 to 60)

- **conduct final data analyses for study** --Will be undertaken at the appropriate time.

- **prepare final report and initial manuscripts** --Will be undertaken at the appropriate time.

KEY RESEARCH ACCOMPLISHMENTS:

None to date.

REPORTABLE OUTCOMES:

Presentations were given to women or representatives of the following: American Cancer Society, Dr. William B. Price Memorial Unit Board of Directors; Lupus and Breast Cancer Awareness Conference; African Health Initiative; Boston Breast Friends' Program; and Center for Community Health Education and Research, Community Research Group. We have successfully implemented a 'Breast Cancer Risk Factors and Healthy Lifestyle' seminar projects for AA women funded by the ACS and TUCCPS as mentioned above. For these projects, we had successfully trained 12 community educators and 6 students on breast cancer risk factors and healthy lifestyle and the importance of our research study. These community educators and students are now able to educate others in these areas. We plan to submit another breast cancer community education grant as women were very appreciative of the information they received from our educational projects and we have been asked by two of our community educators to continue these efforts to reach out to more women.

We were also successful in getting money for a third year of funding to continue a similar research work on premenopausal AA women. We have recently completed data collection for this grant and are in the final phase of data analyses for this study. We are pleased to report from our preliminary analyzes that our results do indicate that women with upper body fat distribution, regardless of obesity level show a hormonal profile associated with increased risk of breast cancer, and that obese women with upper body fat distribution are indeed found to have a premalignant hormonal pattern compared to non-obese women with lower body fat phenotype.

We also presented a poster at the Era of Hope Conference in Orlando, Florida, organized by the DOD Breast Cancer Research Program last September.

CONCLUSIONS:

We are encouraged by our very preliminary findings on the differences in hormone levels between Non-Obese and Obese, as well as between NBF and UBF phenotype postmenopausal AA women, despite the small numbers. We look forward to getting more data in our fourth year that would allow us to test our study hypotheses on the sex hormonal profile of postmenopausal AA women with LBF, NBF and UBF phenotypes.

Although the challenges are great and continue to test our study team at all levels, we are determined to get as many women through the study protocol to meet our study goals as possible. We did satisfactorily in terms of getting an additional 270 interested women last year. This despite what we considered a 'dampened' recruitment effort with the study being on hold for 6 months for reasons beyond our control. As data on this population are limited, it is essential that we continue this work despite all odds. We are recruiting more volunteers to help us with our recruitment efforts, and strategizing new ways to recruit women for the fourth year of this project.

We are encouraged that women welcome presentations on breast cancer risk factors, breast cancer statistics in the AA population, and the importance of our research study. As such we will be making more such presentations within the community to help women understand the work that we do and to dispel any fears and concerns that they may have about research in general, and about going through the study protocol. In addition, being out in the community also help sensitize us further to the needs of the population we are targeting. We continue to persevere with patience and determination to achieve our study goals, learning through our experiences, and incorporating the lessons learned into our future action plans.

Data emanating from this study will add to the virtually non-existent data on the (a) sex hormone profile, and (b) body fat distribution, and body composition of postmenopausal AA women. Significantly more advanced stage, more aggressive, and larger tumors, and higher breast cancer mortality rate in AA women compared to Caucasian women have been observed in several studies (7,8). In addition to answering questions posed by this main study, the data collected for this study may provide a strong foundation for future work to determine factors associated with these reported racial differences in breast cancer outcomes. Valuable data on dietary intake and physical activity levels in this population are also being obtained.

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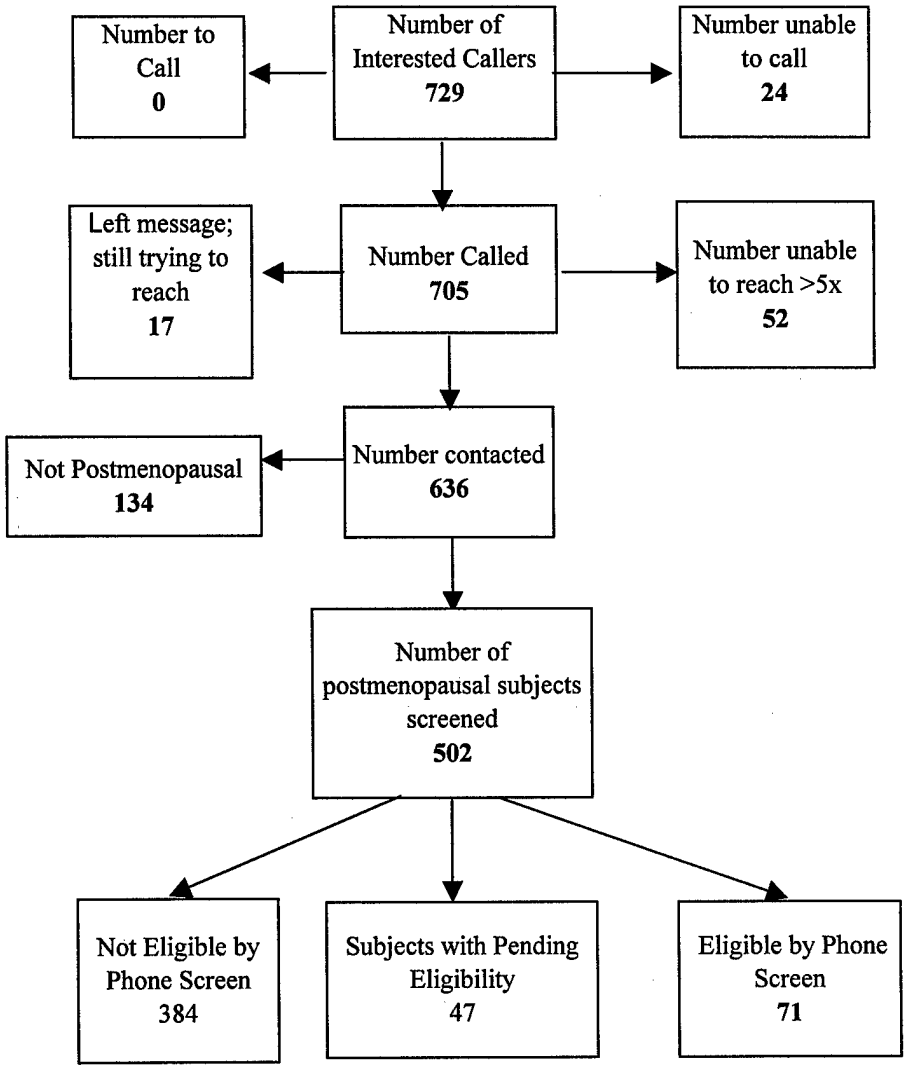
APPENDICES:

Appendix 1: Study recruitment status

Appendix 2: Status of eligible subjects

Tables 1 to 6

Appendix 1. Study recruitment status



Appendix 2. Status of Eligible subjects

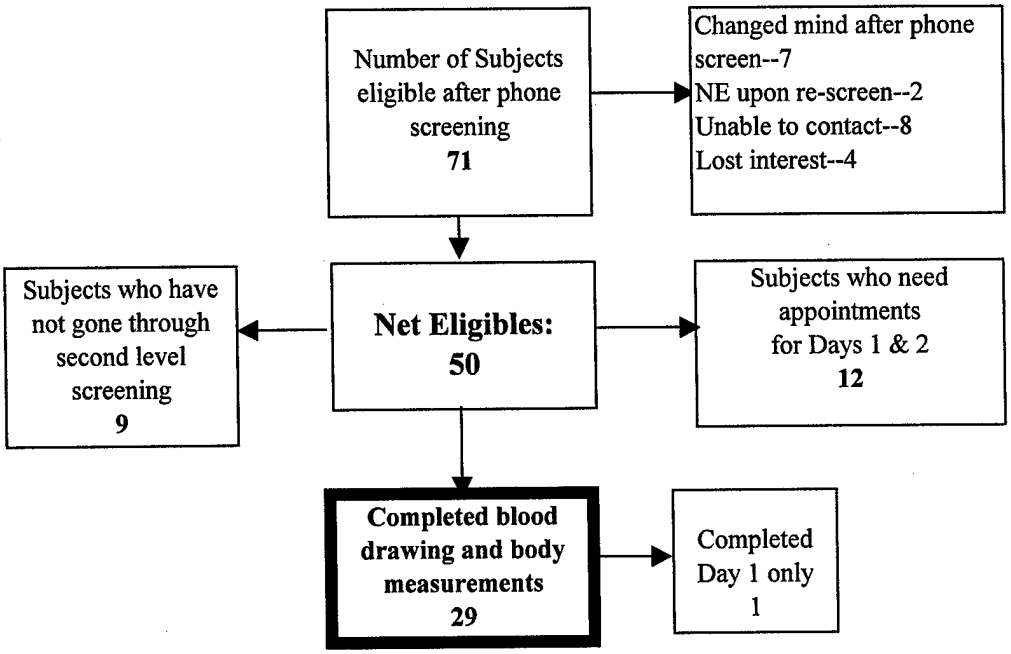


Table 1. Characteristics of all postmenopausal African-American women, and Non-Obese and Obese women

Variables	All women (N=29)		Non-Obese (N=17)		Obese (N=12)		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	p
Age (years)	56.1	6.4	56.1	7.5	56.1	4.7	0.989
Age at menarche (years)	12.9	1.8	12.7	2.0	13.1	1.4	0.542
Age at menopause (years)	49.8	3.6	49.2	4.1	50.7	2.5	0.246
Age at first child (years)	21.1	3.3	21.2	3.7	20.9	3.0	0.799
Number of children*	2.6	1.8	2.5	1.9	2.8	1.8	0.695
Height (m)	1.64	0.08	1.64	0.08	1.65	0.08	0.800
Weight (Kg)	74.0	15.6	64.8	9.5	87.0	13.2	<.0001
Body Mass Index (m/kg2)	27.3	4.5	24.0	2.0	31.9	2.6	<.0001
waist to hip ratio (WHR)	0.80	0.05	0.79	0.05	0.82	0.03	0.091

p values based on student's t-tests for unpaired variables (between Obese and Non-Obese women).
*: For women with children only (N=25)

Table 2. Characteristics of Lower body fat (LBF), Normal body fat (NBF) and Upper body fat (UBF) phenotype postmenopausal African-American women

Variables	LBF Phenotype (N=3)		NBF Phenotype (N=13)		UBF Phenotype (N=13)		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	p
Age (years)	52.3	4.6	56.7	6.5	56.4	6.8	0.907
Age at menarche (years)	12.3	1.5	12.8	2.2	13.1	1.4	0.753
Age at menopause (years)	47.0	2.6	49.8	4.2	50.5	3.0	0.611
Age at first child (years)*	23.0	2.8	21.0	3.0	20.8	3.7	0.892
Number of children*	1.7	2.1	2.5	1.9	2.9	1.8	0.531
Height (m)	1.66	0.11	1.64	0.09	1.64	0.08	0.904
Weight (Kg)	65.6	8.2	69.5	15.6	80.5	15.1	0.080
Body Mass Index (m/kg2)	23.6	0.6	25.5	3.7	29.8	4.5	0.013
Waist to hip ratio (WHR)	0.73	0.01	0.78	0.01	0.84	0.04	<0.0001

p values based on student's t-tests for unpaired variables (between UBF and NBF Phenotype women).
*: For women with children only (N=25)

Table 3. Dietary intake of all postmenopausal African-American women, and Non-Obese and Obese women

Macronutrients per day	All Women (N=29)		Non-Obese (N=17)		Obese (N=12)		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	p
Energy (Kilocalories)	1870	481	1809	496	1957	465	0.422
Total fat (g)	71	25	67	23	78	26	0.264
Polyunsaturated fat (g)	15	8	15	9	15	5	0.974
Saturated fat (g)	23	8	20	7	26	10	0.108
Monounsaturated fat (g)	28	11	26	10	30	12	0.343
Cholesterol (mg)	264	127	242	112	296	145	0.262
Protein (g)	73	22	67	20	83	21	0.052
Carbohydrate (g)	243	74	246	67	240	85	0.815
Fiber (g)	19	9	20	9	18	9	0.589
Alcohol (g)	0.7	1.5	0.6	1.4	0.7	1.6	0.812
Total fat (%)	34	8	33	5	36	10	0.378
Polyunsaturated fat (%)	7	2	7	3	7	2	0.969
Saturated fat (%)	11	3	10	2	12	3	0.211
Monounsaturated fat (%)	13	4	13	3	14	5	0.529
Protein (%)	16	3	15	3	17	4	0.055
Carbohydrate (%)	52	9	55	5	49	12	0.123

P values are based on student's t-tests for unpaired variables (between Obese and Non-Obese women)

(%): Percent calories from the macronutrient indicated.

Table 4. Dietary intake of Lower body fat (LBF), Normal body fat (NBF) and Upper body fat (UBF) Phenotype postmenopausal African-American women

Macronutrients per day	LBF Phenotype (N=3)		NBF Phenotype (N=13)		UBF Phenotype (N=13)		p
	Mean	S.D.	Mean	S.D.	Mean	S.D.	
Energy (Kilocalories)	1936	803	1937	549	1788	343	0.416
Total fat (g)	68	39	75	25	68	22	0.429
Polyunsaturated fat (g)	21	21	16	6	14	4	0.339
Saturated fat (g)	19	6	25	9	21	8	0.274
Monounsaturated fat (g)	22	12	29	10	27	12	0.737
Cholesterol (mg)	314	64	292	155	226	99	0.210
Protein (g)	72	32	76	28	71	12	0.606
Carbohydrate (g)	273	95	248	63	232	82	0.560
Fiber (g)	24	12	19	6	19	10	0.998
Alcohol (g)	0.3	0.3	0.6	1.4	0.8	1.8	0.849
Total fat (%)	30	8	35	4	34	10	0.872
Polyunsaturated fat (%)	8	6	7	2	7	2	0.772
Saturated fat (%)	9	2	11	2	11	4	0.500
Monounsaturated fat (%)	10	3	13	2	14	5	0.786
Protein (%)	15	0	15	2	16	4	0.412
Carbohydrate (%)	58	7	52	5	51	12	0.838

P values are based on student's t-tests for unpaired variables (between UBF and NBF phenotype women)

(%): Percent calories from the macronutrient indicated.

Table 5. Serum Hormone Levels Of All Postmenopausal African-American Women, Non-Obese Women, and Obese Women

	All Women N=29		Non-Obese N=17		Obese N=12		p
Hormones	Gmean	(95% CI)	Gmean	(95% CI)	Gmean	(95% CI)	
Estrogens:							
Estrone (E1)(pg/ml)	35	(29, 42)	33	(26, 41)	38	(28, 51)	0.436
Estrone Sulfate (E1SO4)(pg/ml)	252	(218, 291)	237	(194, 290)	274	(226, 332)	0.336
Estradiol (E2)(pg/ml)	26	(21, 32)	24	(17, 33)	29	(21, 39)	0.449
Free Estradiol (Free E2)(pg/ml)	0.50	(0.40, 0.63)	0.43	(0.31, 0.58)	0.64	(0.47, 0.86)	0.097
% Free Estradiol (%Free E2)	1.93	(1.79, 2.08)	1.79	(1.66, 1.92)	2.15	(1.89, 2.45)	0.014
Androgens:							
Testosterone (T)(ng/ml)	0.18+	(0.13, 0.25)	0.17*	(0.10, 0.26)	0.21	(0.14, 0.31)	0.491
Free Testosterone (Free T)(ng/dl)	2.21+	(1.52, 3.21)	1.70*	(1.03, 2.81)	3.11	(1.83, 5.28)	0.122
% Free Testosterone (% Free T)	1.32+	(1.03, 1.68)	1.03*	(0.92, 1.16)	1.81	(1.10, 2.99)	0.022
Androstenedione (A4)(ng/ml)	0.55	(0.46, 0.66)	0.48	(0.37, 0.62)	0.66	(0.54, 0.81)	0.094
Other:							
Sex Hormone-Binding Globulin (SHBG)(nmol/ml)	65	(53, 78)	81	(69, 96)	47	(33, 65)	0.004
Luteinizing Hormone (mIU/ml)	24	(21, 28)	26	(21, 31)	22	(18, 27)	0.306
Follicular Stimulating Hormone (mIU/ml)	62	(52, 74)	74	(62, 89)	48	(35, 66)	0.020

P values are based on student's t-tests for unpaired variables (between Obese and non-Obese women)

+ : N=28
* : N=16

Table 6. Serum Hormone Levels Of All Postmenopausal African-American Women With Lower Body Fat (LBF), Normal Body Fat (NBF), And Upper Body Fat (UBF) Phenotypes

	LBF Phenotype N=3		NBF Phenotype N=13		UBF Phenotype N=13		p
Hormones	Gmean	95% CI	Gmean	95% CI	Gmean	95% CI	
Estrogens:							
Estrone (E1)(pg/ml)	35	(20, 62)	37	(27, 50)	33	(26, 42)	0.535
Estrone Sulfate(E1SO4)(pg/ml)	366	(225, 594)	245	(196, 307)	237	(197, 286)	0.830
Estradiol (E2)(pg/ml)	22	(10, 49)	25	(17, 37)	27	(20, 37)	0.779
Free Estradiol (Free E2)(pg/ml)	0.37	(0.18, 0.76)	0.46	(0.32, 0.66)	0.59	(0.43, 0.82)	0.322
% Free Estradiol (% Free E2)	1.66	(1.36, 2.03)	1.82	(1.66, 1.99)	2.12	(1.89, 2.39)	0.052
Androgens:							
Testosterone (T)(ng/ml)	0.12	(0.08, 0.17)	0.18	(0.10, 0.33)	0.20*	(0.14, 0.30)	0.773
Free Testosterone (Free T)(ng/dl)	1.03	(0.99, 1.07)	1.87	(0.98, 3.58)	3.19*	(2.04, 4.98)	0.205
% Free Testosterone (% Free T)	0.87	(0.62, 1.22)	1.03	(0.88, 1.20)	1.90*	(1.20, 3.03)	0.018
Androstenedione (A4)(ng/ml)	0.52	(0.40, 0.69)	0.55	(0.41, 0.74)	0.55	(0.42, 0.73)	0.996
Other:							
Sex Hormone-Binding Globulin (SHBG)(nmol/ml)	96	(64, 144)	78	(65, 94)	49	(35, 67)	0.021
Luteinizing Hormone (mIU/ml)	28	(19, 31)	25	(19, 31)	23	(19, 28)	0.688
Follicular Stimulating Hormone (mIU/ml)	76	(63, 92)	61	(42, 90)	60	(51, 70)	0.888

P values are based on student's t-tests for unpaired variables (between UBF and NBF phenotype women)

*: N=12